



**STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT FROM
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY
THE EUROPEAN COMMISSION'S DIRECTORATE-GENERAL FOR HEALTH AND FOOD
SAFETY AND THE EUROPEAN MEDICINES AGENCY**

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) and the European Medicines Agency (EMA) are authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding EU-regulated medicinal products, including pre- and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities.

FDA is authorized under 21 C.F.R. § 20.89¹ to disclose non-public information to DG SANTE and to the EMA regarding FDA-regulated drugs, including pre- and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities. FDA is further authorized under section 708(c) of the Federal Food, Drug, and Cosmetic Act² to share with a foreign government, as it deems appropriate and under limited circumstances, certain types of trade secret information.

The Commissioner of FDA has certified DG SANTE and EMA as having the authority and demonstrated ability to protect trade secret information from disclosure. FDA therefore may provide DG SANTE and EMA with certain types of trade secret information at FDA's discretion and upon request by DG SANTE and EMA, based on the following certifications.

FDA understands that some of the information it receives from DG SANTE and EMA may include non-public information exempt from public disclosure, such as commercially confidential information, trade secret information, private personal information / personal data³, law enforcement information, designated national security information or internal, pre-decisional information. FDA understands that this non-public information is shared in confidence and that it is critical that FDA maintains the confidentiality of exchanged non-public information. Public disclosure of exchanged non-public information by FDA could seriously jeopardize any further scientific and regulatory interactions between DG SANTE/EMA and FDA. DG SANTE and EMA will advise FDA of the non-public status of the information at the time that the information is shared.

¹ United States Code of Federal Regulations, Title 21, section 20.89.

² United States Code, Title 21, section 379(c).

³ In disclosing personal data, DG SANTE and EMA are subject to Regulation (EC) No 45/2001.

Therefore, FDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to it in confidence⁴;
2. will not publicly disclose such non-public information without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal data, or a written statement from DG SANTE or EMA providing that the information no longer has non-public status;
3. will inform promptly DG SANTE and EMA of any effort made by judicial or legislative mandate to obtain non-public information exchanged under the terms of this Statement of Authority and Confidentiality Commitment. If such judicial or legislative mandate orders disclosure of such non-public information, FDA will take all appropriate measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and
4. will promptly inform DG SANTE and EMA of any changes to the United States of America's laws, or to any relevant policies or procedures, that would affect its ability to honor the commitments in this document.

FDA, DG SANTE, and EMA do not intend for this text to create rights and obligations under international or other law. This text partially replaces the Confidentiality arrangement (exchange of letters) between DG SANCO⁵ and FDA concluded on 6 June 2005 and the Confidentiality arrangement (exchange of letters) between EMA and FDA concluded on 14 September 2010 in as far as FDA-regulated drugs and EU-regulated medicinal products are concerned. As a result, the two above-mentioned previous Confidentiality arrangements will remain in effect with respect to information exchanged in accordance therewith on any other products. Information that was considered non-public information under the previous Confidentiality arrangements will continue to be treated as such.

Signed on behalf of FDA


Dara A. Corrigan
Acting Deputy Commissioner
for Global Regulatory Operations and Policy

7/31/2017
Date

⁴ FDA has the authority to protect non-public information under several statutory provisions, including

5 U.S.C. § 552a; 5 U.S.C. § 552(b)(1) – (9); 18 U.S.C. § 1905; and 21 U.S.C. § 331(j).

⁵ DG SANTE was called DG SANCO in 2005. In case of future changes in the organization chart of the Commission regarding assignment of responsibilities between different Directorates-General, this confidentiality commitment will continue to be applicable to the Directorate-General of the Commission which has within its remit responsibility for medicinal products.